IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:

STEWART, et al. Group Art Unit: 1644

Serial No.: 09/438,944

Filed: November 12, 1999 Examiner: DECLOUX, A.

For: COMPOSITIONS AND METHODS FOR PRODUCING VASCULAR OCCLUSION

APPELLANT'S BRIEF ON APPEAL

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APPELLANTS' BRIEF ON APPEAL

1. Real Party In Interest

Applicants and their company, ViRexx Research, Inc., are the parties in interest.

2. Related Appeals

Not applicable.

3. Status Of Claims

(1) Claims 12, 14, 17, 18, and 29-39 are currently pending in this application and are the claims involved in this Appeal. See Appendix A.

(2) Claims 1-11, 13, 15-16, 19-28 were canceled previously and not to be considered as part of this appeal.

4. Status Of Amendments

An Amendment after Final was filed on June 20, 2002. In an Advisory Action mailed July 17, 2002, the Amendment filed June 20, 2002 was not entered because the amendment raises new issues and because the amendment is not deemed to have placed the application in better form for appeal.

5. Summary Of The Invention

The invention is a method for producing a vascular occlusion (e.g., a thrombus) by immobilizing von Willebrand Factor (vWF) at a target site (e.g., a tumor site), and using the natural function of the vWF to bind and activate platelets, which in turn causes the a thrombus to form (page 1, lines 16-19). The invention relies on the natural function of vWF to bind and activate platelets (page 2, line 15 to page 3, line 5). The invention further relies on the natural function of platelets, when activated, to form a thrombus (page 3, lines 6-21).

The technology of the present invention mimics the cell-based, physiologic response to vascular damage. Specifically, immobilizing VWF to a target site leads to platelet deposition, even in the absence of the coagulation protein cascade. Example 8 demonstrates that platelets were found to localize, activate and aggregate at a target site even when the coagulation protein cascade was inhibited (i.e. anti-coagulated blood). Including a human Fc component to the targeting agent was shown to enhance the rate and extent of platelet activation and aggregation about the target site. This Fc component specifically increased platelet activation in synergy with the immobilized VWF (solid-phase

platelet binder) by engaging a receptor on the surface of the platelet, in the absence of a functioning coagulation cascade. However, in the absence of the cellular components of blood (specifically platelets), immobilization of VWF to a target site did not produce a thrombus, nor did the immobilized VWF activate the coagulation protein cascade.

The novelties of the present invention include, (i) specific localization of a cell (platelets) to a target site using an immobilized platelet binder, and (ii) a platelet-dependent initiation of thrombus generation versus a coagulation protein-dependent initiation of a thrombus.

In all of its steps, the method of the present invention includes:

1. Site is targeted (e.g., in proximity to tumor, or tumor cell itself, or pre-determined molecule)
2. Targeting moiety also binds vWF
3. vWF captured at site
4. vWF captures unactivated platelets
5. Platelets activate
6. Platelets aggregate, mediated by vWF and soluble fibrinogen
7. Platelet plug formed, clot formed

Of these various steps, the use of immobilized vWF to capture and activate platelets is novel. The other steps – targeting a site, the elements for binding vWF, vWF capturing platelets and activating them, platelet aggregation, and thrombus formation – all are either well known constructs or processes, or are well known and well described natural processes. The technology of the present invention follows the chronological sequence of the normal hemostatic response, whereby circulating platelets contact and bind to exposed subendothelium activate and aggregate thereby forming a platelet plug that prevents further blood loss from the damaged blood vessel (refer to Ruggeri, 2000).

6. Issues

(1) Whether claims 12, 14, 17, 18, and 29-39 are definite under 35 U.S.C. 112, second paragraph.

(2) Whether claims 12, 14, 17, 18, and 29-39 are enabled under 35 U.S.C.